REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 8-19 and 23-31 (with claims 10, 11, 13, 23, 24, and 26 withdrawn from consideration by the examiner) presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Acknowledgement has been made of applicants' claim for foreign priority based on Israeli application 120792 filed May 7, 1997, but the examiner also states that applicant did not file a certified copy of the Israeli priority application in parent application 09/423,398 as required by 35 U.S.C. §119(b). It is again respectfully pointed out however, that parent application 09/423,398 is a 371 national stage application of PCT/IL98/00211 filed May 6, 1998. MPEP 1828 states that:

> Under the PCT procedure, the applicant may file the certified copy of the earlier filed national application together with the international application in the receiving Office for transmittal with the record copy, or alternatively the certified copy may be submitted by the applicant to the International Bureau or the receiving Office not later than 16 months from the priority date or, if the applicant has requested early processing in any designated Office, not later than the time such processing or examination is requested. The International Bureau will normally furnish copies of the certified copy to the various designated Offices so that the applicant will not

> normally be required to submit certified copies to each designated Office. (emphasis added)

The Notification of Acceptance of Application Under 35 U.S.C. 371 and 37 CFR 1.494 or 1.495 mailed March 3, 2000 by the USPTO in parent application 09/423,398 indicates that the priority document was indeed received. This certified copy of the priority application was furnished by the International Bureau and therefore submission by applicants of a certified copy directly to the USPTO is not required. Applicants again state their request that the examiner indicate for the record in the next Office Action that a certified copy of the Israeli priority document was received in parent application no. 09/423,398.

The examiner states that this application contains claims 8i-ii and iv, 9i-ii and iv, 10-11, 13, 23, 24, 26 and 29 (in part) drawn to inventions non-elected with traverse in Paper No. 10. Applicants repeat their request of reconsideration for this requirement for restriction. MPEP 803.4 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectually property without creating an

> undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applicants Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).
>
> It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases **up to** ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together. (emphasis added)

As disclosed at page 20, paragraph 0071, of the specification, human muscle AchR α-subunit exists as two isoforms of 437 and 462 amino acid residues, which are identical except for a 25 residue insertion (encoded by the 75 bp exon p3A) after residue 58 in the extracellular domain of the longer isoform. Claim 8 is now generic for the amino acid sequences of SEQ ID NO:2, 4, 6, and 8 (SEQ ID NOs:1, 3, 4, and 7 are nucleotide sequences that encode SEQ ID NOs: 2, 4, 6, and 8) by reciting the critical residues that are common to these sequences and which would only require a single search. As these sequences are structurally similar and are within the number of sequences that constitute a reasonable number for examination purposes pursuant

to MPEP 803.04, the presently pending claims should be examined together. At least the restriction requirement with respect to the sequences should be restated as an election of species requirement in which SEQ ID NOs:1 and 2 are the elected species, if the requirement is not withdrawn altogether.

In the event that the requirement is not withdrawn, it is requested that cancellation of non-elected claims be held in abeyance as 37 CFR §1.144 permits deferral of a petition until after a final action but before an appeal is filed.

New claims 8-9, 12, 14-19 and 28-31 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention. The examiner states that, in contrast to applicants' assertions on page 10 of the response, no such basis for "comprising residues 61-76 of SEQ ID NO:2 and/or residues 184-210 of SEQ ID NO:2" in base claim 8 exists in the paragraph (#0080) bridging pages 24 and 25 of the specification.

The erroneous reference to the paragraph bridging pages 24 and 25 is regretted. The basis for support is instead found in the preceding paragraph (#0079) on page 24.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 8-9, 12, 14-19 and 28-31 have been rejected under 35 U.S.C. §112, first paragraph,, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No. 11.

This rejection is obviated by the amendments to the claims which delete, without prejudice, recitation of "fragments" and "at least 95% sequence identity".

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

The amendment of claims 8 and 9 to recite the feature of a fused polypeptide in which the human acetycholine receptor α-subunit portion does not assume the native conformation of the human acetylcholine receptor α-subunit is supported by the specification in the paragraph bridging pages 25 and 26.

Claims 8-9, 12, 14, 16-19, and 30 have been rejected under 35 U.S.C. §102(b) as being anticipated by Schoepfer et al. (1988). This rejection is respectfully traversed.

Schoepfer cannot anticipated the presently claimed invention because Schoepfer's disclosed amino acid sequence of

full length actylcholine receptor has a Val residue at residue 33 instead of Ala. Furthermore, claims 8 and 9 are now amended to use the closed "consisting of" language.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 8-9, 12, 14, 16-19 and 28-30 have been rejected under 35 U.S.C. §102(b) as being anticipated by Talib et al. (1991). This rejection is obviated by the amendments to claims 8 and 9 to use the closed "consisting of" language, to delete recitation of "fragments", and to add the feature required of the fused polypeptide (vi).

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 8-9, 12, 14, 16-19, 25, and 27-30 have been rejected under 35 U.S.C. §102(b) as being anticipated by Barchan et al. (1995). The examiner states that Barchan teaches isolation of a human AChR DNA that encodes a polypeptide inherently capable of suppressing the autoimmune response of an individual to the acetylcholine receptor, which comprises or consists of the nucleotides 1 to 363 and nucleotides 364 to 630 of SEQ ID NO:1, as well as the fusion of any or all fragments of SEQ ID NO:1. This rejection is respectfully traversed.

Contrary to the examiner's assertion, the only fragments which can be loosely interpreted as consisting of

nucleotides 1-363 and nucleotides 364-630 are from species other than human. For instance, the Fig. 2 cited by the examiner shows an alignment of mouse, cat, shrew and hedgehog AChR nucleotide sequences consisting of nucleotides 364-615 (not 630). As the claims are now amended to delete the recitation of "fragments" without prejudice, Barchan cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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